

TITLE Determine way of crimping woven Endoprostheses. Book No. 303

27

From Page No. 27

Scheduled time to Crimp Tubes. (woven Ends).

Attempted crimping with the following methods:

- Mechanic Crimping (Heard rolls)
- Circular Crimping (Hot water bath + shrink Tube)
- Spiral Crimping (winding yarn on to Tube compressed, + Heat set).

Material used: Woven Endoprostheses Grafts  
12 mm, Flat filling yarns.  
Batch # 3.Mechanical Crimping: (AD 000004) [Graft I.D.  $\approx$  13.5 mm]

Sample #	Roll speed set	Hache #	Roll Temp of	Roll Pitch	mandrel. Mandrell Size (mm)	Comments:
1	5	4	329-348 Set - 330	12 ppi	11 mm	Fabric wrinkles as it turns causing wrinkle setting as it goes through the rollers.
2 A	10	7	325-328 (325 set)	12 ppi	14 mm	same problem, tried Temp. set at 300°F, shows no improvement.
2 B	10	7	315	12 ppi	10 mm	Fabric wrinkle even worse.

Circular Crimping: (AD 000003) [Hot bath + shrink Tube]  
Graft I.D.  $\approx$  13.5 mmSample # 3

\* Inserted sample on grooved mandrel, mandrel size 12 mm,  
 submerged sample with shrink tube + grooved mandrel into Hot water tank  
 at 190° ± 10°F for 2.5'. Cooled in cold water for 1.5'

To Page No. 28

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Rectular Crimping C.T. The sample did not crimp at all. This method is mostly for knitted.

Spiral Crimping = (AD 000002).

Sample #4 Graft I.D. = 13.5 mm.

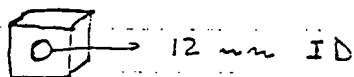
Used the laid to wind on yarn at X turns per inch on to graft placed on a steel mandrel.

Graft I.D. = 13.5 mm

Mandrel O.D. = 12 mm (straight).

Yarn wound = 840 denier Nylon.

- Nylon was wrapped at 10 tpi on to sample
- Sample wound was completely compressed using perforated block



- Once sample was compressed was placed in Autoclave. 250 °F. total of 6-7 min. (Regular Fast cycle)
- Sample removed from mandrel and stretched.
- in Autoclave for an Elongation cycle. (ADCCCCCS)  
(1' at 250 ° ± 5 °F, 15.12 psi, all steam removed and 3' Dry cycle).

To Page No. 29

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From Page No. 28

With the spiral crimping the sample crimped but there was a folded edge because the graft I.D. was too big (13.5 mm) compare to the mandrel 12 mm (straight).

To solve the problem above mentioned will shrink to fit the tubes with dry heat for better fit on the mandrel, so to eliminate the folding on one side.

The shrink to fit is done as AD000043 but without compressing the graft. This is done using a dry heat oven and using teflon mandrels. The graft is placed on to the teflon mandrel, and <sup>(small)</sup> clips are placed to hold the sample straight. The oven is heated to  $175 \pm 5^\circ\text{C}$ , the samples are placed in the oven for 15' at  $175^\circ\text{C}$ , then removed. Now samples are ready for crimping.

To Page No. 30

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From Page No. 29

HEAT SET ON ~~DRY HEAT OVEN~~

(Using teflon mandrels, done to shrink to fit woven tubes. So to fit on steel mandrel for Spiral Crimping).

SHRINK TO FIT (on dry heat oven):

Sample #	Length (cm)		I.D. (mm)		Oven Temp. (°C)	Time (min)	Mandrel Size (mm)	Comments:
	Before	After	Before	After				
3/29 5		56	13.5	12.5	175°	15'	12	Teflon mandrel - Rat tubes shrank away eliminating wrinkles & folding - Tube edges still present
6		56.5	13.5	12.0	175°	15'	12	
4/13 9		2	13.5	12.5	175°	15'	12.0	Steel mandrels
	10	24	13.5	12.5	175°	15'	12.5	
								Aorta Steel mandrel.

## SPIRAL CRIMPING:

Sample #	Compacted Length (cm)		I.D. (mm)		A-clave Temp. (F)	Time (min)	Mandrel Size (mm)	Windings (TPI)	Comments:
	Before	After	Before	After					
4/12 5			12.5	12.5	250°	1' steam 2' dry	12	8	(Steel mandrel) Some wrinkles
4/13 6			12.0	12.6	250°	1' steam 2' dry	12	8	better (less wrinkles)
4/13 9			12.5	12.5	250°	1' steam 2' dry	12	8	
10			12.5	12.5	250°	1' steam 2' dry	12	8	

## ELONGATION CYCLE:

Sample #	Length (cm)		I.D. (mm)		A-clave Temp. (F)	Time (min)	Comments:
	Before	After	Before	After			
4/12 5			12.5	12.5	250°	0.5' steam 2' dry	Clamped on steel mandrel.
4/13 6			12.6	12.6	250°	0.5' steam 2' dry	
4/13 9			12.5	12.5	250°	0.5' steam 2' dry	
10			12.5	12.5	250°	0.5' steam 2' dry	

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Sample #6 sent to Dr. Chuter ST - steam cycle  
Rochester Gen. Hospital, N.Y. dry - dry cycle  
Cat. # SSRAA109-6

To Page No. 31

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TITLE Determine way of Crimping Woven End

From Page No. 30

HEAT SET ON ~~AUTOClave~~ STEAM OVEN

(Using steel mandrels, done to shrink to fit woven tubes. So to fit on steel mandrel for Spiral Crimping).

SHRINK TO FIT (on Autoclave oven):

Sample #	Length (cm)		I.D. (mm)		Oven Temp. (F)	Time (min)	Mandre Size (mm)	Comments:
	Before	After	Before	After				
4/12 7	50.3	50.3	13.5		250	1.5 hr 2 dry	12	Steel mandrel
8	58	58	13.5		250	1.5 hr 2 dry	12	

## SPIRAL CRIMPING:

Sample #	Compacted Length (cm)		I.D. (mm)		A-clave Temp. (F)	Time (min)	Mandre Size (mm)	Windings (TPI)	Comments:
	Before	After	Before	After					
4/12 7	2.5	14	12.5	12.5	250	1.5 hr 2 dry	12	8	Steel mandrel
8			12.5	12.5	250	1.5 hr 2 dry	12	8	

## ELONGATION CYCLE:

Sample #	Length (cm)		I.D. (mm)		A-clave Temp. (F)	Time (min)	Comments:
	Before	After	Before	After			
4/12 7	14	13 3/4			250	0.5 hr 2 dry	on 12 mm steel
8					250	0.5 hr 2 dry	mandrels.

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st - Steam cycle  
dry - dry cycle

To Page No. \_\_\_\_\_

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